IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of: Stephen D. Pacetti et al.

Examiner: Erma C. Cameron

Art Unit: 1762

Serial No: 10/680,905

Filed: October 7, 2003

For: System And Method For Coating A Tubular Implantable Medical Device

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.131

I, Stephen D. Pacetti, declare as follows:

1. I, along with co-inventor Hung Manh Le, conceived of the subject matter of claims 9, 12-15 and 22 of the application identified above prior to May 20, 2003.

2. I have attached a copy of an Invention Disclosure Form (Exhibit A) prepared and signed by me, Stephen D. Pacetti, prior to May 20, 2003 which was submitted to the assignee of the present application for preparation of a patent application.

3. The Invention Disclosure Form clearly sets forth the invention of at least claims 9, 12-15 and 22. Specifically, pages 3-7 of the Invention Disclosure Form describe and illustrate a method of forming a layer of a composition that includes a polymer and a solvent on the surface of an applicator substrate and rotating a tubular implantable medical device along a longitudinal central axis of the device while a surface of the device is in close proximity to or in contact with a surface of the applicator substrate, as recited in claim 9 of the invention. See Figures 1, 2 and 3.

In addition, the Invention Disclosure Form describes and illustrates a method of coating an implantable medical device that additionally includes leveling the composition on the surface of the applicator so that the layer has substantially uniform thickness, as recited in claim 22 of the invention. See the top figure on the page entitled Roller Coating a Drug Eluting Stent and the bottom figure of notebook page 53.

4. Outside counsel worked with diligence in preparing the present application from just before May 20, 2003 to October 7, 2003, the filing date of the present application. Outside counsel took up cases on his or her docket in chronological order and carried out the preparation of the application expeditiously.

5. Conception of the claimed invention, at least claims 9, 12-15 and 22, and preparation of the Invention Disclosure Form were carried out in the United States at 3200 Lakeside Drive, Santa Clara, CA 95052.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Executed at Santa Clara, California on this 18 day of October, 2007.

By: Stephen Pacetti
Stephen D. Pacetti

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111-3492
Telephone (415) 954-0200
Facsimile (415) 393-9887

DECLARATION UNDER 37 CFR §1.131

EXHIBIT A

GUIDANT CONFIDENTIAL & PRIVILEGED

For Legal Department Use Only
Docket No.: 3623
Date Assigned: 7/24/02
Date Discl. Rec'd: JUL 25 2002

Doug Deburg

INVENTION DISCLOSURE FORM

ADVANCED CARDIOVASCULAR SYSTEMS, INC.

This is a form for disclosing ideas and inventions to the Guidant Legal Department for patent consideration. This form may be used before experimental work has been done. While some of the requested information may not be available at this time, include as much information as you can about the invention. Attach additional sheets if necessary, and sign and date each sheet. Additional information will be requested later.

Please complete each indicated area and return to Intellectual Property Paralegal, Guidant Vascular Intervention Group, 3200 Lakeside Drive, Santa Clara, CA 95052, and a copy to the R&D Director.

File

1. DESCRIPTIVE TITLE OF THE INVENTION **Roll Coating Process for a Drug Eluting Stent**

KEY WORDS: **Drug Eluting Stent, Roll Coating**

2. **Submitter(s)**: *(please provide your full name, including middle name)*

Inventor 1			
Full Name: **Stephen Dirk Pacetti**		**Signature:** Stephen Pacetti	
Home address: **4578 Madoc Way**	City: **San Jose**	State: **CA**	Zip **95130**
Citizenship: **USA**	Home phone no.: **408-370-1496**		
Work no.: **408-845-3452**	Work fax no.: **408-845-3222**		
Empl. No. **017953**	Division Name: **Stent Business Unit**	Manager Name: **Robert McGreevy**	

Inventor 2			
Full Name: **Hung Manh Le**		**Signature:** Hung Manh Le	
Home address: **2082 Treewood Lane**	City: **San Jose**	State: **CA**	Zip: **95132**
Citizenship: **USA**	Home phone no.: **408-942-1210** Retired		
Work no.: **408-845-1384**	Work fax no.: **408-845-3333**		
Empl. No.	Division Name: **Stent Business Unit**	Manager Name: **Andrew Tung**	

3. Invention Applicability/Project/Release/Sale Information

To which division or operation does this invention best apply? Stent

Field of Technology: Coating process

Related Invention Disclosure Docket Nos.: TBD

Project Name/Description: TBD

Product Name: TBD

Estimated/actual manufacturing release date of invention or product incorporating or using the invention: TBD (date)

Estimated/actual date of offer for sale of product incorporating or using the invention: TBD (date)

(408-845-3000

Inventors initials:
1 SP 2 HL 3____ 4____ 5____ 6____ 7____ 8____ 9____

(a) Describe the invention in as much detail as possible, and include a description of a working prototype, if any. Write your description using reference numerals placed on a drawing. Point out and explain relationship with associated equipment. (b) How is the invention used? (c) How does it relate to present or potential commercial products of the company or others? (d) State the significance of the invention, and any problems it is intended to solve. Please supplement when possible by attaching sketches, engineering drawings, pages from lab books, photographs, and the like.

INTRODUCTION

Currently, most drug eluting stents are coated by a spray process. However, many other stent coating processes are possible. There is also an interest in minimizing the amount of polymer on the stent. While this can be done by reducing the thickness of the coating to a minimum, there are particular stent surfaces where the drug/polymer coating is probably more effective. For example, the Cook stents in the ELUTES and ASPECT trials had drug only on the stent OD, and yet still where quite effective. Consequently, new stent coating techniques, which only coat the OD of the stent, may have utility.

Roll, or web, coating is the generic name for a family of coating techniques. What is in common to all of them is that the coating is first applied to a surface; often a roller of some kind, and then the part to be coated is contacted with the roller. This technique is often used to coat large surface areas with precision coatings. Floppy disc magnetic media, videotape, backing with pressure sensitive adhesive, and even Post-Its are, or have been, coated by roll coating.

(a) DISCLOSURE

What is disclosed is a roll coating process to coat just the outer surface of a drug eluting stent. In general, the process first consists of applying the wet coating to a flat surface, or a roller. The stent is then contacted with this surface. In the case of a flat surface, the stent is rolled on the thin film. For this to work, the stent must be translated while it is rolled at a speed so that the stent does not skid or slide. Essentially, the stent is simply rolled on the coating. If the translating speed is not correct, the stent will accumulate coating and become webbed. A schematic is shown below.

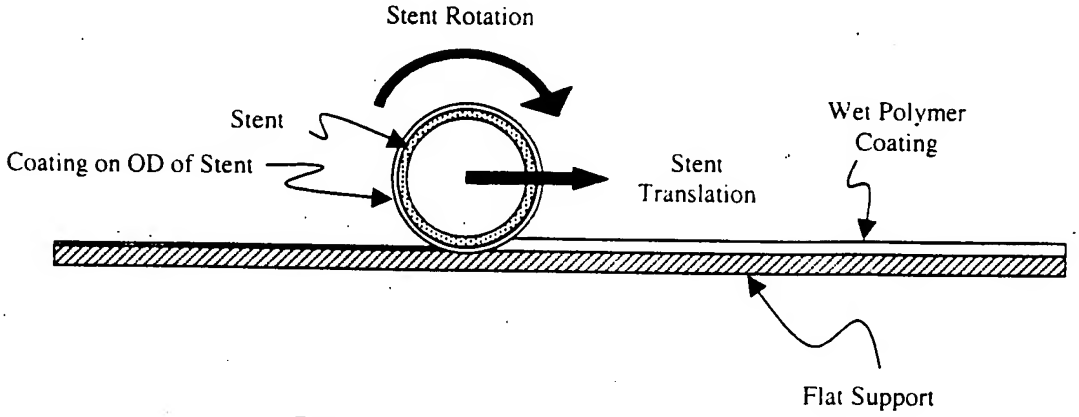

Figure 1. Roll coating a stent on a flat sheet

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For this to work several conditions must be met.

- The wet coating on the flat support must be very thin, not much thicker than the strut thickness.
- The viscosity of the coating solution must be quite high. It must be great enough to overcome surface tension forces that could create webbing. The coating should only transfer to the stent where the stent touches the wet coating. The coating cannot be allowed to flow once it is on the stent or it will cause webbing.
- As already discussed, the rotation and translation speed of the stent must be matched so that the stent just rolls along the surface picking up coating.

EXAMPLE

Small VISION stents, 12 mm long, were pre-expanded to 0.069. They were weighed and mounted onto 0.070" OD stainless steel hypotubes. A bead of an 20% solution of fat free EVAL (EC-151A) in dimethylacetamide was applied to the surface of a 316L, stainless steel coupon. This bead was made into a thin film by dragging a glass slide, held lengthwise, down the coupon. The glass slide was used essentially as a Doctor's blade or drawdown bar. A single VISION stent mounted onto a hypotube was then carefully laid down at one end of the thin film. By grasping each end of the hypotube, the stent was rolled a short distance along the wet polymer film. The coated stents were then baked at 80C for 1 hr. Afterwards, the stents were slid off of the mandrels, inspected under the light microscope, and weighed.

Below are images of stent A rolled coated with a 20% solution of EVAL/DMAC.

Figure 1. Overall view of stent A

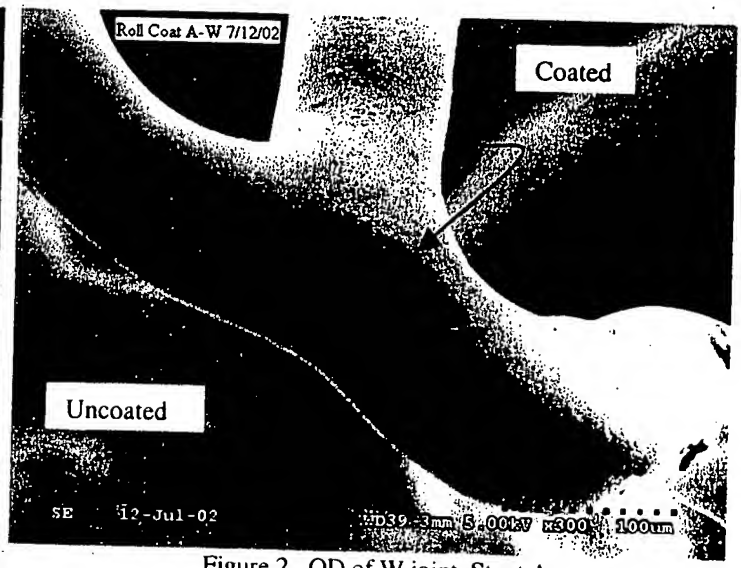

Figure 2. OD of W joint, Stent A.

Figures 1 and 2 show the coating on the OD of the stent, with it coming a third down the sidewalls.

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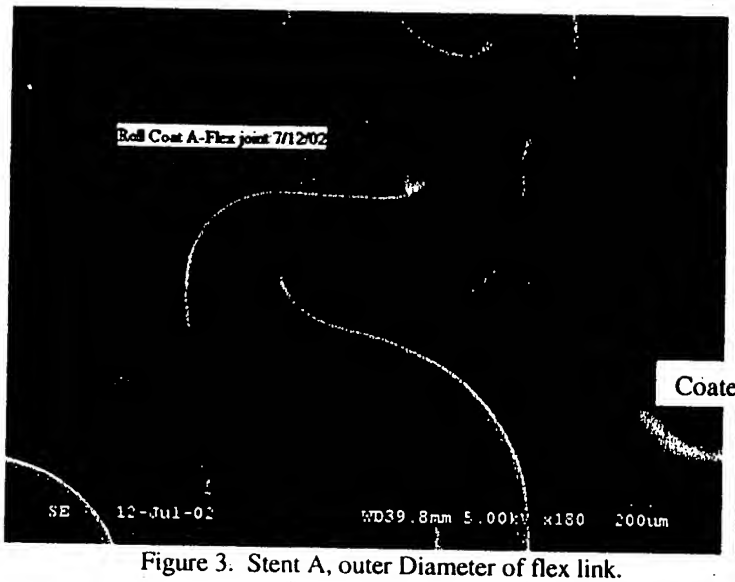

Figure 3. Stent A, outer Diameter of flex link.

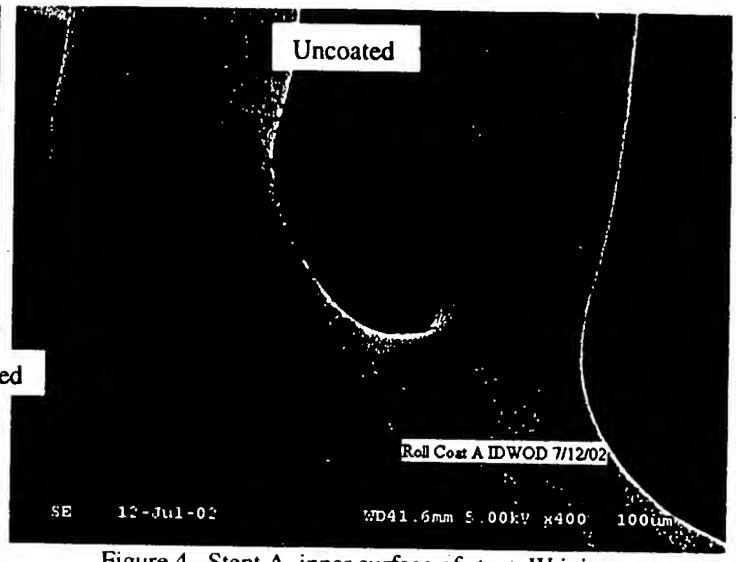

Figure 4. Stent A, inner surface of stent, W joint.

Figure 3 shows the coating on the OD of a flex link with a small web in the flex link. Figure 4 is of the stent ID. We see the coating wrapping around the sidewalls some, but no coating on the ID. There is, however, dirt on the ID as the stents were processed on a lab bench. This stent had only 70 ug of polymer on it. This may not seem like much. However, the coating is only on the OD and maybe one third of the strut sidewalls. With most Guidant stents, 25% of the total surface area is on the OD, 25% of the surface area is the ID, and 50% of the surface area is on the sidewalls. This is the distribution with struts that are nearly square in cross section. With this in mind, 70 ug of coating that is only on the OD and 1/3 of sidewalls is equivalent to a 170 ug of coating that is uniformly coated all stent surfaces. Below are images of stent C that was coated similarly.

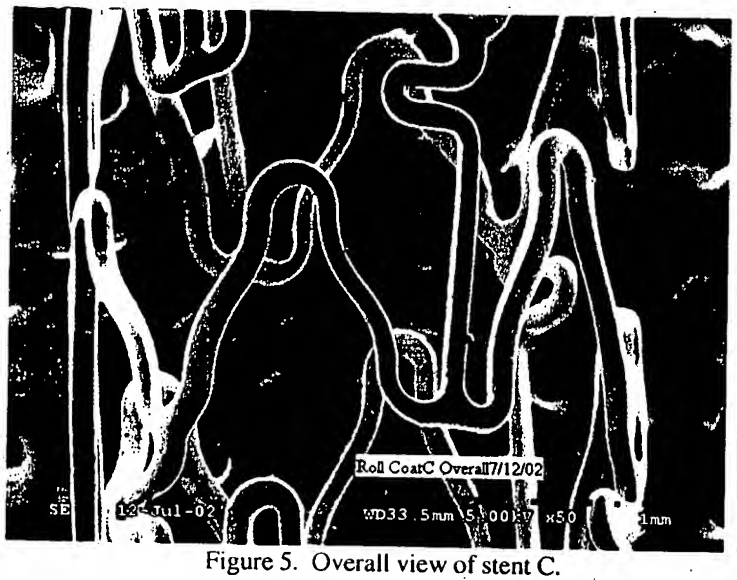

Figure 5. Overall view of stent C.

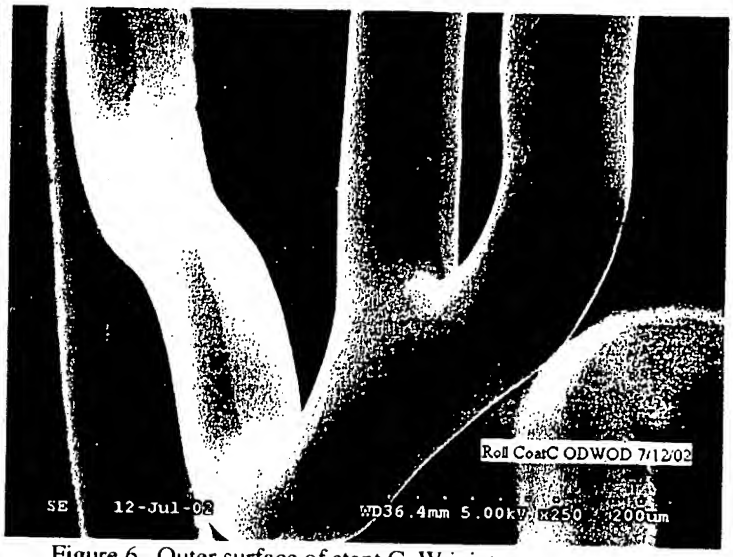

Figure 6. Outer surface of stent C, W joint.

This stent had less polymer on the sidewalls than stent A. However, the total coating weight was also less at 43 ug.

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An issue encountered with these experiments was some of the stents sticking to the hypotube after baking. Stents A and C did not stick. If an excess of coating was applied, or if too thick a coating was applied, the coating would get on the stent ID, bonding the stent to the hypotube. This can be avoided by making the wet coating very thin. It may also help to not use a stainless steel hypotube as a mandrel, but instead to use something less wettable like a teflon rod. In addition, other stent fixturing methods may be better than a cylinder inside of the stent. If the wet coating is first applied to a roller of some kind, then there are many schemes to transfer the wet coating to the stent. Below is a scheme for reverse roll coating.

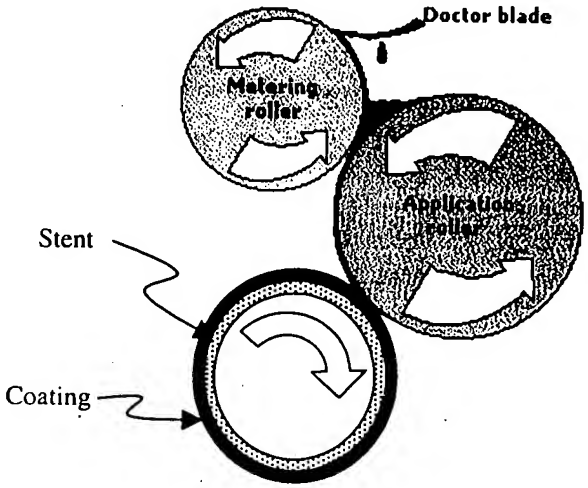

Figure 2. Reverse roll coating a stent.

Below is a scheme for gravure coating a stent.

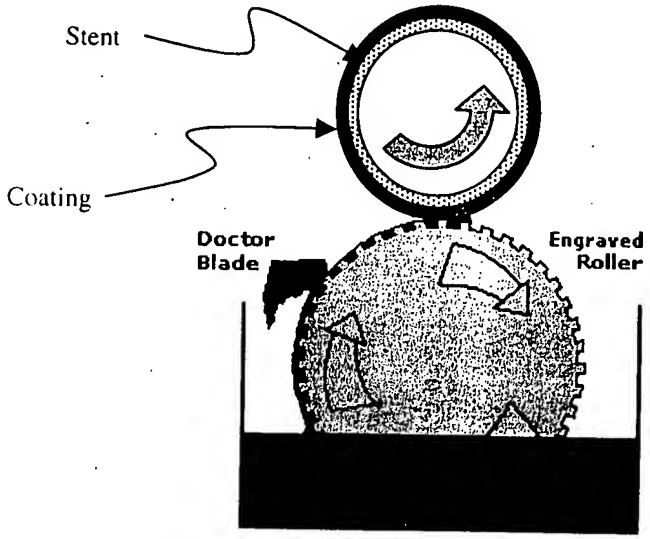

Figure 3. Gravure coating of a stent.

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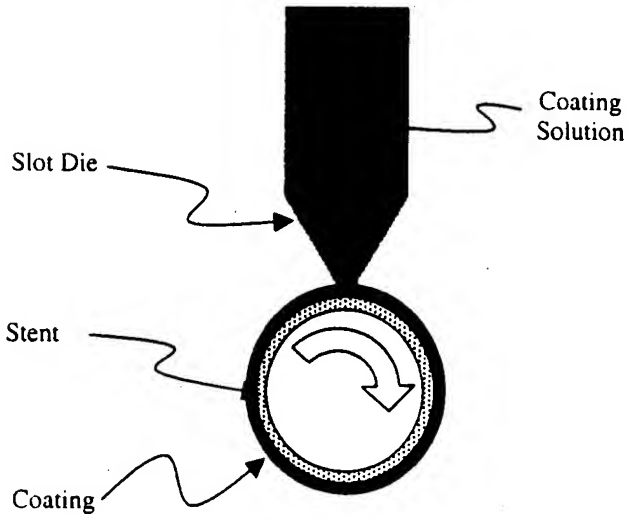
Next is shown slot die coating of a stent OD.



Slot die coating of the stent OD is a type of roll coating as the stent is rotated under the slot. It would be quite challenging as the gag between stent and die, stent rotation, and fluid pump speed would have to be precisely controlled. There is also the issue of starting and stopping the process for each stent.

There are advantages and disadvantages for each stent coating process. For roll coating, an attempt to summarize these is listed in the table below.

Roll Coating, Advantages and Disadvantages

+	-
Can selectively coat the stent OD	Limited amount of coating can be applied in one pass
Can coat high viscosity or particle laden solutions	Process must be automated with precision
No atomization. Can be done in a fume hood	Requires high percent solids solution.
Fast process for 70 ug on a 12 mm stent	Wet surfaces can attract particulates

5. PROJECTED GENERIC SCOPE

Describe the invention in terms of the ***broadest*** generic scope which you expect will be operable (e.g. if a machine or article, describe alternate type and sizes of materials for construction, etc.; if a process, describe alternate manufacturing conditions, etc.).

A roll coating process could be used on any drug eluting stent. Such coatings can be used on balloon expandable or self-expanding stents. This stent may be utilized in any part of the vasculature including neurological, carotid, coronary, renal, aortic, iliac, femoral, or other peripheral vasculature. There are no limitations on stent length, diameter, strut thickness, strut pattern, or stent material.

Inventors initials:
1 JP 2 HL 3____ 4____ 5____ 6____ 7____ 8____ 9____

6.

Has a literature search been made? Yes_____No __X____Don't know_____

If "Yes", list and if possible, attach copies of all literature, publications, patents and applications of which are relating to the invention. See section in Guidelines for Completing Invention Disclosure Form concerning obligation of disclosure.

Is this invention an improvement of an existing company product? Yes__X___ No _____ Don't know_____
If "Yes" identify the product: Drug Delivery Stent

List the closest known prior art/technology: __TBD___

7. Publication of the Invention

What is the current stage of development of the invention? _Concept____

Has a description been published or is it scheduled to be published? Yes_____ No __X___ Don't know_____
Has a description been disclosed or is it scheduled to be disclosed outside of Guidant?
Yes_____No __X____Don't know_____

If "Yes", when and to whom? _____

Was a Non-Disclosure Agreement used? Yes_____No _____Don't know_____

If "Yes", please attach a copy of the agreement to the disclosure.

8. Joint Development of Development Contract

Was this invention made under a government agency contract? Yes_____No __X____Don't know_____

If "Yes":
• List all non-Guidant inventors: _____

• List all government contract numbers: _____

9. Witness Signature (not a submitter)

Read and understood the completed Invention Disclosure Form

N. (Nadine) Ding
Printed Name

[signature] 7/24/02
Signature Date

Inventors initials:
1 SP 2 HL 3____ 4____ 5____ 6____ 7____ 8____ 9____

BOOK NO.

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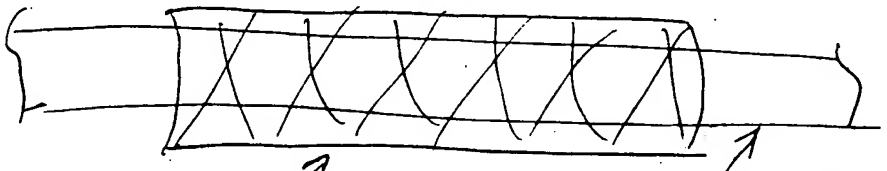
3/15/02 Roller Coated Stent

The Boch-Paclitaxel technology places the drug only on the OD of the stent. The efficacy of this system, demonstrates that you only need drug on the outside of the stent.

The stent can be spray coated on the OD if we spray coated onto a stent that was mounted on a large mandrel.



The large mandrel blocks the inner surface of the stent from being spray coated.

Another common coating technique is roll coating. Roll coating a stent would coat just the stent O.D. A large question is whether roll coating will cause webbing. Webbing may be controlled by adjusting the viscosity of the coating solution.

The stent will be held by a mandrel which fits inside the stent snugly

The coating on the roll will have a wet coating thickness less than the strut thickness.

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SIGNATURE Stephen Pacetti DATE 3/20/02

DISCLOSED TO AND UNDERSTOOD BY DATE WITNESS DATE

3/26/02

52. TITLE Roller Coating a Drug Eluting Stent

PROJECT NO.

BOOK NO.

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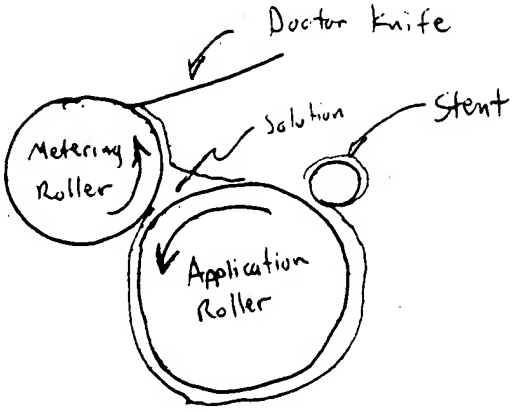
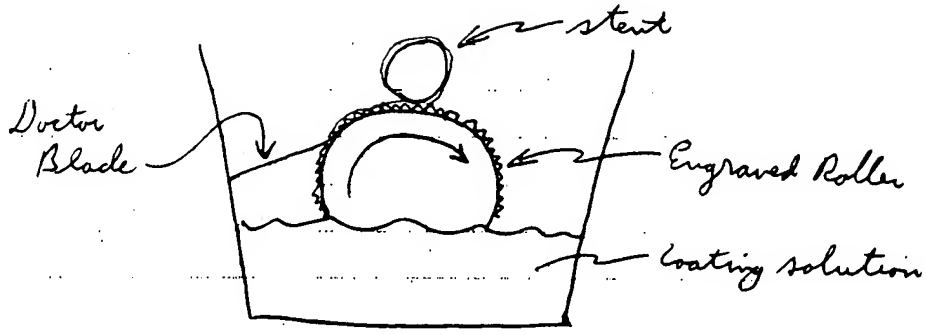


This is a type of reverse roll coater for a stent

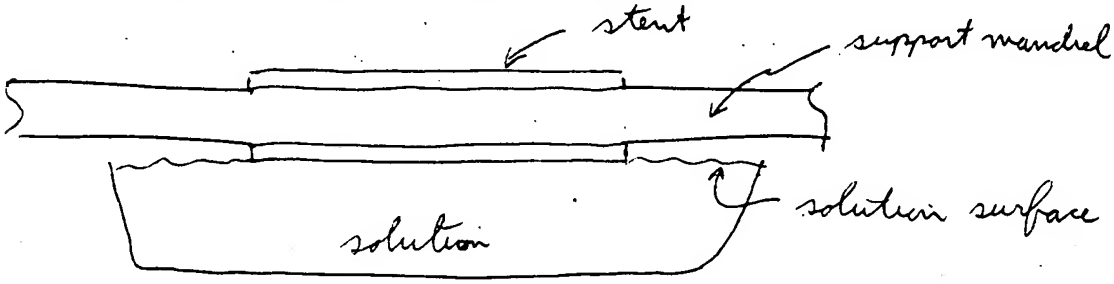
Gravure coating for a stent

In gravure coating a textured roller contacts the stent



Since the stent has a finite circumference, there is the question of how many times you allow the stent to roll 360°. It is coated after a single rotation. Multiple rotations may be needed to assure overall uniformity.

In another coating technique a stent on a mandrel is brought down close to the solution surface



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SIGNATURE Stephen Pacetti DATE 3/20/02

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03/26/02

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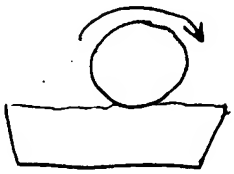
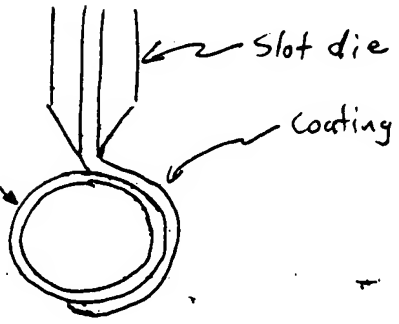
The stent is rotated as it just touches the surface of the solution



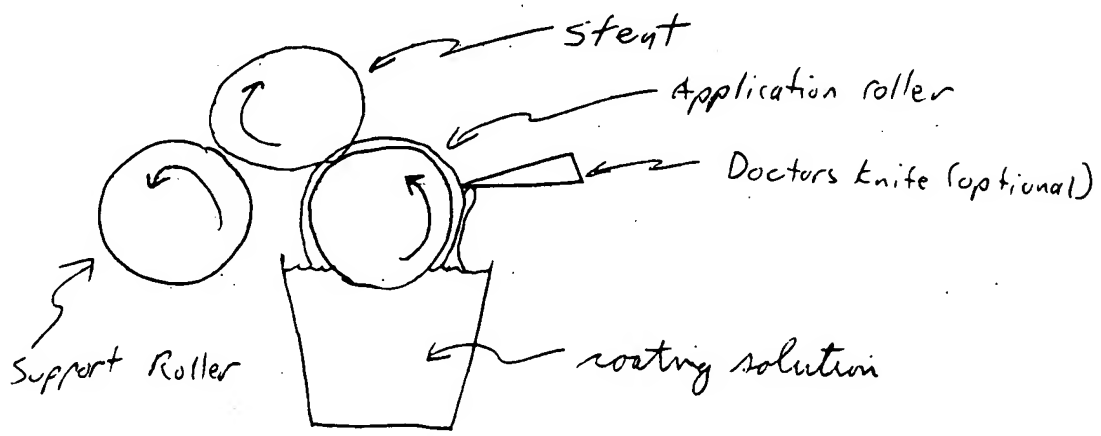
The OD of the stent is coated. Webbing has to be controlled by using the correct viscosity.

Slot die coating of a stent



For all of these techniques, the objective is just to apply a small number of coats. 1–3, for example.

Another roller coating method for a stent



The stent is rolled for 1+ revolution. Then it is removed and baked

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SIGNATURE Stephen Pacetti DATE 3/26/02

DISCLOSED TO AND UNDERSTOOD BY Andrew Fay DATE 03/26/02 WITNESS DATE